

other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.*** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

## T. Congressional and Other Federal Investigations and Actions

188. The United States Department of Justice ("DOJ"), the United States General Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating the drug manufacturers for questionable practices regarding the industry's calculation of AWP and for offering illegal incentives to providers.

189. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of

the trade organization known as the Pharmaceutical Research and Manufacturers of America (most of the Defendant Drug Manufacturers are members of this association), Congressman Stark identified the improper scheme of manipulating AWP's and noted:

This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.

**U. Defendants' Unlawful Conduct**

190. Defendants' drugs, including but not limited to Gonol-F, Serostim and Rebif are all in competition with other drugs.

191. To compete, Defendants' salespersons offered doctors who make prescribing decisions financial inducements if they used Serono's drugs. These inducements included discounts, free goods, and other benefits that lowered the actual cost of the drugs so that the doctor made a profit on the spread between AWP and the cost of the doctor. These discounts, inducements and free goods were not reflected in reported AWP's.

**V. CLASS ACTION ALLEGATIONS**

192. Plaintiff brings this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of itself and the Class comprised of:

All persons or entities who, for purposes other than resale and during the Class Period, paid any portion of the purchase for Cetrotide®, Crinone®, Gonol-F®, Fertinex®, Ovidrel®, Pergonal®, Profasi®, Rebif®, Saizen®, and Serostim® at a price calculated by reference to the AWP.<sup>1</sup>

Excluded from the Class are: (a) each defendant and any entity in which any defendant has a controlling interest, and their legal representatives, officers, directors, assignees and successors; (b) any co-conspirators; and (c) any governmental entities who purchased such drugs during the

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<sup>1</sup> Plaintiff reserves the right to modify the Class Definition based on class related discovery and/or merits discovery.

Class Period. Included in the Class are end payors and consumers who made a pro rata co-payment or who paid cash.

193. The Class Period is January 1, 1996 to the present.<sup>2</sup>

194. The Class consists of numerous individuals and entities throughout the United States, making individual joinder impractical, in satisfaction of Rule 23(a)(1). The disposition of the claims of the Class Members in a single class action will provide substantial benefits to all parties and to the Court.

195. The claims of the representative plaintiff are typical of the claims of the Class, as required by Rule 23(a)(3), in that the representative plaintiff is an entity who, like all Class Members, as a result of defendants' deceptive and unlawful scheme, paid for drugs that were medically unnecessary as a result of prescriptions that were based on diagnostic devices that were scientifically unproven. The representative plaintiff, like all Class Members, has been damaged by defendants' misconduct because, among other things, it paid for drugs that it would not have paid for but for defendants' improper actions.

196. The Class representative for the Class is the only plaintiff.

197. The factual and legal bases of each defendant's misconduct are common to the Class Members and represent a common thread of fraud and other unlawful misconduct resulting in injury to plaintiff and members of the Class.

198. There are many questions of law and fact common to plaintiff and the Class, and those questions predominate over any questions that may affect individual Class Members, within the meaning of and fulfilling Rules 23(a)(2) and 23(b)(3). Common questions of law and fact include, but are not limited to, the following:

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<sup>2</sup> The exact dates for the Class Period may be refined based upon discovery.

- a. Whether defendants promoted the use of unapproved, adulterated and unproven medical devices and computer software and distributed these devices to physicians. Whether defendants trained, authorized and encouraged sales representatives to administer the purported body cell mass wasting tests to AIDS victims to fraudulently induce physicians to prescribe Serostim.
- b. Whether the defendants paid illegal inducements and kickbacks to physicians to induce them to prescribe Serostim;
- c. Whether defendants fraudulently encouraged physicians to order Serostim in quantities that their patients did not need or could not consume;
- d. Whether defendants had physicians sign blank prescription forms for Serono sales representatives to complete and ordered Serostim under falsified physician signatures;
- e. Whether defendants marketed Serostim to physicians for the treatment of lipodystrophy, a separate condition involving weight gain in the mid-section and weight loss in the extremities, for which Serostim was not approved by the FDA;
- f. Whether AWP for Serono drugs are used as a benchmark for negotiating payments by third-party payors for drugs;
- g. Whether defendants engaged in a course of conduct that improperly inflated AWP used by plaintiff and Class Members as the basis for reimbursement;

- h. Whether defendants artificially inflated the published AWP's for the drugs that are the subject of this complaint;
- i. Whether defendants engaged in a pattern and practice of unlawful acts that caused plaintiff and Class Members to make inflated payments for products with deceptively inflated AWP's;
- j. Whether defendants engaged in a pattern of deceptive and/or fraudulent activity intended to deceive and/or defraud plaintiff and the Class Members;
- k. Whether defendants are liable to plaintiff and the Class Members for damages for conduct actionable under the various state consumer protection statutes;
- l. Whether defendants are liable to plaintiff and the Class Members for damages for conduct actionable under various state law provisions for unjust enrichment.
- m. Whether defendants engaged in a pattern and practice of unlawful acts that caused plaintiff and Class Members to make payments for products which patients did not need;
- n. Whether defendants engaged in a pattern of deceptive and unlawful activity intended to defraud plaintiff and the Class Members;
- o. Whether defendants are liable to plaintiff and the Class Members for damages for conduct actionable under the various state consumer protection statutes; and

- p. Whether defendants are liable to plaintiff and the Class Members for damages for conduct actionable under various state law provisions for unjust enrichment.

199. Plaintiff will fairly and adequately represent and protect the interests of the Class, as required by Rule 23(a)(4). Plaintiff has retained counsel with substantial experience in prosecuting nationwide consumer class actions. Plaintiff and its counsel are committed to vigorously prosecuting this action on behalf of the Class, and have the financial resources to do so. Neither plaintiff nor its counsel have any interest adverse to those of the Class.

200. Plaintiff and members of the Class have all suffered, and will continue to suffer, harm and damages as a result of defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive, and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the Courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to plaintiff and the Class and require Court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

**CAUSES OF ACTION**

**VI. COUNT I: THE SEROSTIM MEDICAL DEVICE ENTERPRISE: VIOLATION OF 18 U.S.C § 1962**

201. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

202. Defendants are “persons” within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of enterprise, the Serostim Medical Device Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

203. The Defendants participated in associations-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Serono, including its employees and agents, RJL, Liedtke, and other persons unknown. The Serostim Medical Device Enterprise was an ongoing organization that functioned as a continuing unit. The enterprise was created and used as tools to effectuate a pattern of racketeering activity. The Defendants are “persons” distinct from the enterprise.

204. Defendants and the other members of the Serostim Medical Device Enterprise created and maintained systematic links for a common purpose: to aid in the unlawful promotion of Serostim for medically unnecessary and unproven purposes based on use of medical devices and software that had not been scientifically validated. Each of the participants in the enterprises received substantial revenue from the scheme to promote Serostim. Such revenue was greater than it would have been if Serostim had been marketed lawfully. All participants were aware of Defendants’ control over the activities of the Serostim Medical Device Enterprise. Furthermore, each portion of the Serostim Medical Device Enterprise benefited from the existence of other parts.

205. The Serostim Medical Device Enterprise engaged in and affected interstate commerce, because, among other things, it marketed, sold, purchased, or provided Serostim to thousands of individuals throughout the United States.

206. Defendants have exerted control over the Serostim Medical Device Enterprise and management of the affairs of the Serostim Medical Device Enterprise.

207. Defendants have conducted and participated in the affairs of the Serostim Medical Device Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud) and U.S.C. § 1343 (wire fraud).

208. Defendants distributed the adulterated and unapproved medical devices and associated software in interstate commerce and used mail and interstate wire communications and interstate travel to create and manage its fraudulent scheme. Defendants' scheme involved national marketing and sales plans and programs, and encompassed the deployment of sales representatives, and impacted victims, across the country.

209. Defendants' use of the mails and wires to perpetrate its fraud involved communications, including, but not limited to:

- a. marketing materials and training resulting in diagnostic training that was known by Defendants not to be unapproved and scientifically unproven, resulting in prescriptions for Serostim that were medically necessary, such materials being sent to doctors across the country;
- b. communications with physicians that fraudulently misrepresented the medical conditions for which Serostim could be prescribed;
- c. communications with health insurers and patients, inducing payments for Serostim, to be made based on misrepresentations concerning the medical



necessity and usefulness of Serostim; and

d. receiving the proceeds of Defendants' improper scheme.

210. In addition, Defendants' corporate offices have communicated by United States mail, telephone, and facsimile with various sales directors and pharmaceutical representatives in furtherance of Defendants' scheme.

211. Defendants' pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under U.S.C. § 1343. Defendants' fraudulent scheme consisted of, inter alia: deliberately misrepresenting the conditions for which Serostim was necessary so that Plaintiffs and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be necessary; and actively concealing and causing others to conceal information about the true necessity of Serostim to treat patients suffering from AIDS.

212. In implementing its fraudulent scheme, Defendants were acutely aware that plaintiff and members of the Class depended on the honesty and integrity of Defendants in representing the medical necessity of Serostim's uses to physicians and to plaintiff and those similarly situated. It is impractical and unduly expensive for the Class Members or the physicians who treated them to perform their own medical device and computer software testing or assemble all known medical evidence relating to Serostim's necessity. Class Members also rely on federal law obligating Defendants to provide fair and balanced information about their drug products and the medical devices they promote to determine the necessity of using such products and reasonably presume that medical devices promoted by Defendants' are unadulterated and approved for their intended use and that Defendants' testing

of the medical devices and associated software and Serostim complied with Defendants' obligations under federal law.

213. Defendants' scheme was calculated to ensure that Plaintiffs and the Class would pay for Serostim for medically unnecessary purposes.

214. The conduct of the Serostim Medical Device Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decision for the Serostim Medical Device Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

215. Defendants' fraudulent marketing scheme depended upon its concealing its use of unapproved and adulterated medical devices and software and unproven testing from physicians, consumers and third-party payors. These activities and others described above concealed Defendants' fraudulent promotional activities and consumers and third-party payors could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence.

216. The earliest Plaintiffs could have reasonably become aware of the fraudulent marketing scheme was 2005.

217. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendants are estopped from relying on any statute of limitations to defeat any of Plaintiffs' claims.

218. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and the members of the Class.

219. Plaintiffs and members of the Class have been injured in their business and property by reason of these violations in that Plaintiffs and members of the Class have made millions of dollars in payment for Serostim that they would not have made had Defendants not engaged in its pattern of racketeering activity. By reason of the unlawful acts engaged in by Defendants, Plaintiffs and the Class have suffered ascertainable loss and damages.

220. Plaintiffs' and members of the Class' injuries were directly and proximately caused by Defendants' racketeering activity as described above.

221. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiffs and the Class for three times the damages Plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

**VII. COUNT II: THE SEROSTIM PHYSICIAN KICKBACK ENTERPRISE: VIOLATION OF 18 U.S.C § 1962(C)**

222. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

223. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of enterprise, the Serostim Physician Kickback Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

224. The Defendants participated in associations-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Serono, including its employees and agents, and paid Serono consultants, and other persons unknown. The Serostim Physician Kickback Enterprise was an ongoing organization that functioned as a continuing unit. The enterprise was created and used as tools to effectuate a pattern of racketeering activity. The Defendants are “persons” distinct from the enterprise.

225. Defendants and the other members of the Serostim Physician Kickback Enterprise created and maintained systematic links for a common purpose: to aid in the unlawful promotion of Serostim for medically unnecessary purposes. Each of the participants in the enterprise received substantial revenue from the scheme to promote Serostim. Such revenue was greater than it would have been if Serostim had been marketed lawfully. All participants were aware of Defendants’ control over the activities of the Serostim Physician Kickback Enterprise. Furthermore, each portion of the Serostim Physician Kickback Enterprise benefited from the existence of other parts.

226. The Serostim Physician Kickback Enterprise engaged in and affected interstate commerce, because, among other things, it involved interstate travel and communications among the members of the enterprise, generate interstate mail and wire communications, and resulted in Serostim being sold, purchased, or provided to thousands of individuals throughout the United States.

227. Defendants have exerted control over the Serostim Physician Kickback Enterprise and management of the affairs of the Serostim Physician Kickback Enterprise.

228. Defendants have conducted and participated in the affairs of the Serostim Physician Kickback Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud) and U.S.C. § 1343 (wire fraud).

229. Defendants have used interstate travel and mail and interstate wire communications, to create and manage its fraudulent scheme. Defendants' scheme involved a national marketing campaign, referred to as the "\$6m-6 Day Plan," and encompassed the deployment of sales representatives to meet with physicians across the country. Defendants' use of the mails and wires to perpetrate its fraud involved communications, including, but not limited to:

- a. transmission of airplane tickets and wire payments and reimbursements, as inducements for the prescription of Serostim;
- b. provision of financial benefits to the physicians relating to the medically unnecessary prescription of Serostim;
- c. communications that fraudulently misrepresented the benefits of Serostim to physicians;
- d. communications with health insurers and patients, inducing payments for Serostim to be made based on misrepresentations concerning the medical necessity usefulness of Serostim; and
- e. Receiving the proceeds of Defendants' improper scheme.

230. In addition, Defendants' corporate offices have communicated by United States mail, telephone, and facsimile with various sales directors and pharmaceutical representatives in furtherance of Defendants' scheme.

231. Defendants' pattern of racketeering activity includes acts such indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under U.S.C. § 1343. Defendants' fraudulent scheme consisted of, among other things, deliberately misrepresenting the conditions for which Serostim was necessary so that Plaintiffs and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be necessary; and actively concealing and causing others to conceal information about the true medical necessity of Serostim to treat AIDS.

232. In implementing their fraudulent scheme, Defendants were acutely aware that plaintiff and members of the Class depended on the honesty and integrity of Defendants in representing the medical necessity of Serostim's uses to physicians and to plaintiff and those similarly situated. It is impractical and unduly expensive for the Class Members or the physicians who treated them to perform their own evaluation of the medical evidence relating to Serostim's necessity. Class Members also rely on federal law obligating Defendants to provide fair and balanced information about the drug products they promote to determine the necessity of using such products and reasonably presume that the testing of Serostim to determine its medical necessity complied with Defendants' obligations under federal law.

233. Defendants' scheme was calculated to ensure that Plaintiffs and the Class would pay for Serostim for medically unnecessary purposes.

234. The conduct of the Serostim Physician Kickback Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decision for the Serostim Physician Kickback Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

235. Defendants' fraudulent marketing scheme depended upon its concealing the illegal payments to physicians from consumers and third-party payors. These activities and others described above concealed Defendants' fraudulent promotional activities and consumers and third-party payors could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence.

236. The earliest Plaintiffs could have reasonably become aware of the fraudulent marketing scheme was 2005.

237. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of Defendants' conduct. Accordingly, Defendant is estopped from relying on any statute of limitations to defeat any of Plaintiffs' claims.

238. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and the members of the Class.

239. Plaintiffs and members of the Class have been injured in their business and property by reason of these violations in that Plaintiffs and members of the Class have made millions of dollars in payment for Serostim that they would not have made had Defendant not engaged in its pattern of racketeering activity. By reason of the unlawful acts

engaged in by Defendant, Plaintiffs and the Class have suffered ascertainable loss and damages.

240. Plaintiffs' and members of the Class' injuries were directly and proximately caused by Defendant's racketeering activity as described above.

241. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiffs and the Class for three times the damages Plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

**VIII. COUNT III: VIOLATION OF U.S.C. § 1962(D) BY  
CONSPIRING TO VIOLATE 18 U.S.C. § 1962(C)**

242. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

243. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

244. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the enterprises described previously through a pattern of racketeering activity.

245. Defendants and their co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs and the Class of money.

246. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were aware that their



ongoing fraudulent and illegal acts have been and are part of an overall pattern of racketeering activity.

247. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs and the Class have been and are continuing to be injured in their business or property as set forth more fully above.

248. Defendants sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

- a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;
- b. Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;
- c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346.

249. Defendants' violations of the above federal laws and the effects thereof detailed above continued over a course of time. Plaintiffs and members of the Class have been injured in their property by reason of these violations in that Plaintiffs and members of the Class have made millions of dollars in payments for Serostim that they would not have made had Defendants not conspired to violate 18 U.S.C. § 1962(c).

250. By reason of the unlawful acts engaged in by Defendants, Plaintiffs and the Class have suffered ascertainable loss and damages. Injuries suffered by Plaintiffs and members of the Class were directly and proximately caused by Defendants' racketeering activity as described above.

251. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are liable to Plaintiffs and the Class for three times the damages Plaintiffs and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

**IX. COUNT IV: VIOLATION OF STATE CONSUMER PROTECTION STATUTES**

252. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

253. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they concealed that their use of medical devices and associated software were not approved or scientifically proven for diagnosis of AIDS wasting, that they made illegal payments to physicians in exchange for gaining commitments to prescribe Serostim, that they made illegal payments to pharmacies in exchange for gaining commitments to alter prescriptions or provide information to be used by the Defendants, in fraudulently promoting Serostim, and generally concealed their knowledge that they were prescriptions for Serostim were medically unnecessary based on testing that had not been proven to be scientifically valid. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs and members of the Class were injured in that they paid millions of dollars for Serostim that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

254. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 44-1522, et seq.

255. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, et seq.

256. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.

257. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, et seq.

258. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, et seq.

259. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, et seq.

260. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq.

261. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, et seq.

262. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.

263. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §10-1-392, et seq.

264. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, et seq.

265. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.

266. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 50511, et seq.

267. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, et seq.

268. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.1 b, et seq.

269. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.

270. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, et seq.

271. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.

272. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation Mass Gen L. Ch. 93A, et seq.

273. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq.

274. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, et seq.

275. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, et seq.

276. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Missouri Stat. § 407.010, et seq.

277. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, et seq.

278. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.

279. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, et seq.

280. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, et seq.

281. Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, et seq.

282. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, et seq.

283. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 et seq.

284. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.

285. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, et seq.

286. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.

287. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, et seq.

288. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.

289. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, et seq.

290. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, et seq.

291. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, et seq.

292. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. code Laws § 37-24-1, et seq.

293. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, et seq.

294. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.

295. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, et seq.

296. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, et seq.

297. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.

298. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, et seq.

299. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, et seq.

300. The unfair and deceptive acts and practices of Defendants have directly, foreseeably, and proximately caused damages and injury to Plaintiffs and the members of the Class.

301. The actions and failures to act of Defendants, including the false and misleading representations and omissions of material facts regarding the lack of proven medical necessity of Serostim and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses, or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression, or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above

302. Physicians, consumers, and third-party payors relied upon Defendants' misrepresentations and omission in prescribing Serostim to patients. By reason of the unlawful acts engaged in by Defendants, Plaintiffs and the Class have suffered ascertainable loss and damages. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class were damaged by paying for these prescriptions.

303. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and members of the Class are entitled to compensatory damages, treble damages, attorneys' fees and costs of suit.

**X. COUNT V: COMMON LAW FRAUD**

304. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

305. Defendants made misrepresentations and omissions of facts material to Plaintiffs' and Class members', including deliberately misrepresenting the medical necessity

of using Serostim, deliberately omitting to disclose information concerning the lack of scientific validation for their adulterated and unapproved medical device testing process, and other misrepresentations and omissions as set forth herein.

306. Defendants knew at the time that they made these misrepresentations and omissions that they were false or that Defendants had failed to disclose facts it was obligated to disclose in order to make its other representations not misleading. Defendants was aware that physicians, consumers, and third-party payors would rely on these misrepresentations and omissions in making prescribing payment, and reimbursement.

307. Plaintiffs and the Class reasonably relied upon Defendants' misrepresentations and omissions of material fact. Plaintiffs and the Class had no reason to doubt the veracity or scientific validity of the testing procedures Defendants promoted through their marketing and sales strategies.

308. Defendants' misrepresentations and omissions of material fact directly and proximately caused Plaintiffs' and the Class's damages.

309. By virtue of the fraud they perpetrated on Plaintiffs and the Class, Defendants are liable to Plaintiffs and the Class for all damages Plaintiffs and the Class have sustained, plus punitive damages, plus the cost of this suit, including attorney's fees.

## **XI. COUNT VI: UNJUST ENRICHMENT**

310. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

311. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiffs and the Class made for Serostim.



312. In exchange for the payments they made for Serostim, and at the time it made these payments, Plaintiffs and the Class expected that the drug was medically necessary for the condition, illness, disorder, or symptom for which it was prescribed and the determination of medical necessity was made based on approved and valid testing processes.

313. Defendants have voluntarily accepted and retained the benefit of these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs and the Class paid for Serostim when they otherwise would not have done so. The failure of Defendants to provide Plaintiffs and the Class with the remuneration they expected enriched Defendants unjustly.

314. Plaintiffs and the Class are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits to the extent and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

## **XII. DEMAND FOR RELIEF**

315. WHEREFORE, Plaintiffs and the Class demand judgment against Defendants in each claim for relief, jointly and severally, as follows:

- a. On Plaintiffs' and the Class's RICO claims, three times the damages Plaintiffs and the Class have sustained as a result of Defendants' conduct, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorneys' fees;
- b. On Plaintiffs' and the Class's Consumer Fraud Act claims, compensatory damages, three times the damages Plaintiffs and the Class have sustained as a result of Defendants' conduct, such as amount to be determined at trial, plus Plaintiffs' costs in this suit, including reasonable attorney's fees;

- c. On Plaintiffs' and the Class's common law fraud claim, compensatory damages, punitive damages, such amounts to be determined at trial, plus Plaintiffs' cost in this suit, including all reasonable attorneys' fees;
- d. On Plaintiffs' and the Class's claim for unjust enrichment, recovery in the amount of Plaintiffs' and the Class's payment for Serostim based on prescriptions that supported tests using invalid unapproved medical devices and software, or based on prescriptions that were not supported by medical necessity, such amount to be determined at trial, plus Plaintiffs' costs in this suit, including all reasonable attorney's fees;
- e. Awarding Plaintiffs and the Class other appropriate equitable relief;
- f. Awarding Plaintiffs their costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and
- g. Awarding Plaintiffs and the Class such other and further relief as may be just and proper under the circumstances.

**XIII. DEMAND FOR JURY TRIAL**

Pursuant to Federal Rule of Civil Procedure 38(b) Plaintiffs demand a trial by jury on all issues so triable.

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Dated: November 21, 2005

**CERTIFICATE OF SERVICE**

Docket No. MDL 1456

I, David S. Nalven, hereby certify that I am one of plaintiffs' attorneys and that, on November 21, 2005, I caused copies of Plaintiffs' First Amended Class Action Complaint Against Serono International, S.A., Serono Laboratories, Inc., Serono, Inc., RJL Systems, Inc. and Rudolph J. Liedtke to be served via VeriLaw on all counsel of record in this proceeding via Lexis/Nexis File Serve.

**/s/ David S. Nalven**

Dated: November 21, 2005